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| 10/583,086 | 09/06/2007 | Concetta C. Fiannaca | 118989-06069055 | 8801 |
| 20583 | 7590 | 03/19/2010 | EXAMINER | |
| JONES DAY | | | LE, HOA T | |
| 222 EAST 41ST ST | | | | |
| NEW YORK, NY 10017 | | | ART UNIT | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|----------------------------------------|--|
| Office Action Summary | Application No. 10/583,086 | Applicant(s) FIANNACA ET AL. | |
| | Examiner H. (Holly) T. Le | Art Unit 1794 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>06/15/06 & 07/21/08</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it recites broad ranges, i.e. 80% in similar morphologies and 1.2 or less in monodispersivity index, along with narrower ranges, i.e. 90% & 95% in morphology and 1.0 or 0.6 or less in monodispersivity index. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

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Claim 1 is further indefinite in view of the phrases "preferably" and "especially" because it is unclear whether the limitations following these phrases are part of the claimed invention. See MPEP § 2173.05(d).

Claims 2, 4, 7, 8, 18, and 21 suffer the same deficiency of claim 1.

Claim 4 is further indefinite in view of the phrases "typically" and "usually greater" because it is unclear whether the limitations following these phrases are part of the claimed invention. See MPEP § 2173.05(d).

Claims 13 and 14, "first component" has no clear antecedent basis.

Other claims are deemed indefinite in view of their dependency upon claim 1 or claim 2.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-5, 9-13, 18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No 6,589,579 to Ganan-Calvo ("US'579").

Claims 1 and 2: US'579 teaches particles produced by spray method comprising two components. See col. 2, lines 30-41. The first component is a covering material and the second component is an active ingredient, i.e. food nutrient or drug material (col. 4,

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lines 1-3). The produced particles are highly uniform in size (col. 3, lines 65-67).

Therefore, it necessarily has substantially same morphology and MDI of at most 0.5.

Claim 3: The particles are spherical or hollow spheres (col. 5, lines 21-25).

Claim 4: The produced particles are highly uniform in size (col. 3, lines 65-67).

Therefore, it necessarily has substantially same morphology and MDI of at least 0.2.

Claim 5: The produced particles are highly uniform in size (col. 3, lines 65-67);

therefore, they necessarily substantially have the same morphology.

Claim 9: The process made by US'579 necessarily produces dust-free particles because it's conducted in a closed system. In addition, the particles are food and drug materials; therefore, the basic standard for these materials essentially dust-free.

Claims 11-12: Biocompatible components including sugar and sweeteners (i.e. polysaccharides) are suggested at col. 31, lines 22-27; and methylcellulose and starches are suggested at col. 32, lines 1-9.

Claims 13 and 20: The first component comprises polymer which is a film-forming material.

Claim 18: Active ingredient (i.e. second component) is present up to 80wt% and up to 20% for other component (i.e. first component). See col. 26, lines 50-63.

5. Claims 1 and 3-10 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,628,937 to Oliver ("US'937").*

* Cited by Applicant.

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Claim 1: US'937 teaches solid particles made by spraying method (col. 2, lines 14-24) to produce particles of the same morphology, i.e. spherical (solidified uncoalesced droplets) and monosize droplets. See col. 2, lines 20-23 and col. 3, lines 39-47 and 55-57. Example 2 at col. 12 reports the particle size distribution of the particles. Based on this report, the monodispersivity index (MDI) is calculated as described in the instant specification at page 4 third paragraph, and results is: $[(500 - 200)/400 =] 0.75$ or less.

Claim 3: monosize droplets (col. 3, lines 55-57) mean spherical or at least "roughly spherical"

Claim 4: Example 2 at col. 12 reports the particle size distribution of the particles.

Based on this report, the monodispersivity index (MDI) is calculated as described in the instant specification at page 4 third paragraph, and results in an MDI of 0.75 (i.e. $[(500 - 200)/400]$).

Claim 5: US'937 teaches solid particles made by spraying method (col. 2, lines 14-24) to produce particles of the same morphology, i.e. spherical (solidified un-coalesced droplets) and monosize droplets. See col. 2, lines 20-23 and col. 3, lines 39-47 and 55-57.

Claims 6-8: The particles have a weight mean size of 450 microns (Example 1) and 344 microns (Example 2, col. 12) which necessarily falls within the claimed volume mean size of 100 to 500 microns.

Claim 9: The process made by US'937 necessarily produces dust-free particles because it's conducted in a closed system.

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Claim 10: The particles have the smallest size of 100 microns (Example 2, col. 12); therefore, the volume mean size cannot be less than 80 microns.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 12-17, 19 and 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over 5,628,937 ("US'937") in view of US 6,589,579 ("US'579").

Claim 21: US'937 teaches the claimed particles as discussed above. US'579 teaches a method of making highly uniform particles comprising two components as discussed above. US'937 teaches a method wherein the precursor formulation has a density of 700 to 1500 kg/m³, a viscosity of 0.01 Pa.s, and surface tension of 0.03 to 0.073 N/m; and the liquid jets have a Rej of 10 to 10,000. See US'937, col. 8, lines 64-68 and col. 5, lines 1-3. However, US'937 does not mention Ohnesorge number. US'579 discloses that at an Ohnesorge number of 0.01 to 3.7, any viscosity range of the precursor would not affect the uniformity of the resulting particles. See US'579, col. 18, lines 33-36. Therefore, one of ordinary skill in the art would have been motivated to start a precursor formulation with an Ohnesorge of 0.01 to 3.7 to ease up the limitation in viscosity requirement, and the viscosity as claimed would become simply a matter of choice. In

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addition, US'579 also suggests a Rej number of 500 to 6,000 when two-component particles are desired (US '579, col. 15, lines 55-60). Therefore, one of ordinary skill in the art would be further motivated to optimize the range of the Rej number from the broad range of 10 to 10,000 as taught by US'937 to the specific range of 500 to 6000 as taught by US'579.

Claim 22: Acoustic vibration to prevent coalescence is taught in US'937 (col. 3, lines 55-58).

Claim 23: Weber frequency (fw) used for droplet generation in the range of 5.52 kHz (US'937, col. 10, lines 50-52) or 1-300 kHz (US'579 at col. 4, lines 1-5).

Claim 24: Laminar jet is suggested by US'937 at col. 4, lines 66-67 and col. 10, line 50.

Claims 25-27: See the rejections to claims 21 and 23 above.

Claims 12-17 and 19: The two component particles taught by US'579 are food and drug products; therefore, the materials chosen for the first and second components would have been obvious as a matter of choice that would be suitable as food or pharmaceutical materials.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to H. (Holly) T. Le whose telephone number is 571-272-1511. The examiner can normally be reached on 12:30 p.m. to 9:00 p.m. (EST), Mondays to Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on 571-272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. (Holly) T. Le/
Primary Examiner, Art Unit 1794

March 14, 2010